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1 RECORD OF ORAL HEARING
2 UNITED STATES PATENT AND TRADEMARK OFFICE

3
4 BEFORE THE BOARD OF PATENT APPEALS
5 AND INTERFERENCES

6
7 *Ex Parte* HANS SMOLA and GILBERTO NEPOMUCENO

8
9 Appeal 2010-002821
10 Application 10/596,159
11 Technology Center 1600

12 Oral Hearing Held: April 12, 2011

13
14 Before RICHARD M. LEOVITZ, FRANCISCO C. PRATS, and
15 STEPHEN G. WALSH, *Administrative Patent Judges*.

16 APPEARANCES:

17 ON BEHALF OF THE APPELLANT:

18 RACHEL A. LYNCH, ESQUIRE
19 K&L Gates, L.L.P.
20 Suite 3100
21 70 West Madison Street
22 Chicago, Illinois 60602-4207

23 The above-entitled matter came on for hearing on Tuesday, April 12,
24 2011, commencing at 1:15 p.m., at the U.S. Patent and Trademark Office,
25 600 Dulany Street, Alexandria, Virginia, before Cynthia Sydnor-Thomas, a
26 Notary Public.

P R O C E E D I N G S

JUDGE LEBOVITZ: Okay, we're on record. We are Appeal No. 2010-002821, which is Application No. 10/596,159, is that correct?

MS. LYNCH: Yes.

JUDGE LEBOVITZ: Okay. If you can, introduce yourself and begin when you're ready, and you'll have about 20 minutes.

MS. LYNCH: Sure. Good afternoon. My name's Rachel Lynch. As you said, I'm here for Appellants for Serial No. 10/596,159. So this Appeal includes just one obviousness rejection, and, as I'm going to argue and as I hope you will agree, that the rejection is improper as a matter of fact and law. So before I get into the actual arguments, I'd like to walk you through a little bit about our invention.

Specifically, Appellant has discovered that combining specific amounts of proline and arginine synergistically enhance wound healing. So as discussed in the Specification, proline's provided in the nutritional composition in an amount that helps facilitate halogen synthesis.

Now, arginine has also been found to help with wound healing, as discussed in the specification, but Appellant has found that simply combining these two ingredients together doesn't necessarily optimize wound healing for the patient or the consumer of the composition. Instead, arginine is a metabolic precursor for nitric oxide which acts as a vasodilator and enhances growth hormone secretion. So as is discussed in-depth in the Specification, it's not optimal for critically ill patients to be exposed to high amounts of nitric oxide, so Appellant has found that if you include specific amounts of proline and arginine you can optimize and create a delicate balance of the two to administer to these patients for wound healing.

1 JUDGE LEBOVITZ: I thought I heard you use the term synergistic?

2 MS. LYNCH: Yes.

3 JUDGE LEBOVITZ: Do you have any evidence in the Specification
4 or by declaration of synergy?

5 MS. LYNCH: We do not. We do have an experimental example in
6 the Specification that shows a drastic benefit when a consumer is
7 administered specific amounts of proline. We do not have in the
8 Specification a specific example of the specific amounts combined.

9 So Appellants are going to argue that the skilled artisan would have
10 no reason to combine *Gray* and *McEwen* because *Gray* teaches away from
11 the combination of *McEwen* as well as the present claims. Moreover,
12 references must be considered as a whole, and those portions that teach away
13 from the claimed invention must be considered. For example, the Examiner
14 cites *Gray* for the disclosure of a composition for wound healing having
15 protein lipids, carbohydrates, and proline and arginine. As discussed in the
16 Specification, however -- I'm sorry, in Appellants' Appeal Brief, *Gray*
17 expressly states that at least 3 percent of the total calories must be present
18 from arginine and that enhanced wound healing with arginine is believed to
19 be provided at quantities greater than 3 percent of the total calories.

20 Now, in the disclosure of *Gray*, they go even further to say that the
21 composition should have a "high arginine content and that in choosing the
22 protein source the present invention maximizes the natural availability of
23 arginine." So repeatedly throughout *Gray* they're saying you have to have a
24 minimum of 3.0, and even greater than that is where you find enhanced
25 wound healing. So this is in direct contrast to what Appellant is saying,
26 which is that not more than 1.8 percent of the total calories should be

1 provided by arginine. And this isn't just a random limitation for arginine. It
2 actually has a physiological benefit, as stated previously, in that it's a
3 metabolic precursor to nitric oxide which is -- can actually provide
4 complications for wound healing instead of aiding in wound healing.

5 So instead of having, you know, 3 percent or more, Appellants are
6 specifically saying you need to have a low amount of arginine and we
7 require not more than 1.8 percent. So we have purposely limited the amount
8 of arginine that can be present in our nutritional compositions. *Gray* is not
9 at all concerned with potential physiological disadvantages and, as I said,
10 actually requires maximizing the amounts of arginine provided. So in effect,
11 *Gray* would lead the skilled artisan down a path that is divergent from that
12 taken from Appellant in this case, that is, that *Gray* requires maximizing or
13 at least 3 percent. We require no more than 1.8, which is almost half that
14 and required to be less than that.

15 JUDGE LEBOVITZ: Do you have any disclosure in your
16 Specification about why those amounts were chosen? I know you're
17 alluding to it or talking about it, but is that disclosed in the Spec?

18 MS. LYNCH: A specific reason why?

19 JUDGE LEBOVITZ: Yes.

20 MS. LYNCH: Is not disclosed. Generally, during this kind of
21 inventive process there is a reason, probably, you know, was done --
22 experimental tests were done in developing this product, which is why 1.8
23 was chosen. We just did not have that disclosed in our Specification.

24 JUDGE PRATS: But you do say at page 2 of the Spec, starting at
25 about line 9 I think it is, you do talk about, which you later argued, that

26

1 arginine can lead to excess nitric oxide formation, so that -- you do have to
2 have a reason for doing it.

3 MS. LYNCH: Yes. That is the reason. You know, it provides a
4 physiological benefit to not have a metabolic production of nitric oxide in
5 vivo. So, you know, if we can limit the amounts of arginine that we're
6 providing, we'll reduce the metabolic pathway that will lead to the
7 production of nitric oxide, so that is the reason that we do it. The specific
8 amount of 1.8 is not disclosed, but we do --

9 JUDGE LEBOVITZ: Well, because I think on that page of the Spec,
10 looks like page 1, it looks like the inventor here is acknowledging that 1 to 3
11 percent of the total energy intake is preferably provided by arginine. So that
12 actually overlaps.

13 MS. LYNCH: That was for a different U.S. Patent, so we're
14 discussing prior art there and that -- you know, saying that 1.3 in that patent
15 is what was preferred, and we're saying 3 is too high. We have now done
16 tests, we figured out that you can't have that much arginine in there because
17 it could convert to nitric oxide.

18 JUDGE LEBOVITZ: Yeah, but it does seem to acknowledge that you
19 could also use less than 3 and 1 to 3, so that does overlap with your range,
20 right?

21 MS. LYNCH: It does overlap with our range but, as we're claiming
22 here, we need both arginine and proline, so we're going for a synergistic
23 balance of the two. So we've now shown in our Specification that if you use
24 certain amounts of proline that it helps with wound healing. We're also
25 saying we've discovered that it can be, you know, unbeneficial to provide
26 too high amounts. So now we're saying certain amounts of proline and, oh,

1 by the way, also don't give too much arginine because this could be very bad
2 for the patient.

3 JUDGE WALSH: The Examiner relied on *McEwen* reference as
4 teaching 1 percent arginine?

5 MS. LYNCH: Yes, that's correct.

6 JUDGE WALSH: And I gather you think that was an error, right?
7 Why isn't that appropriate?

8 MS. LYNCH: We do because the problem here is combining the two
9 references. So you have *Gray* which teaches you cannot give more than this
10 and, in fact, maximize it, and in fact let's give as much as possible with a
11 very minimum of 3. So now the Examiner comes in with *McEwen* and says
12 okay, well, this discloses 1, so let's just combine the two.

13 We're saying, you know, the minimum amount required by *Gray* is 3,
14 and they're teaching that it has to be at least 3. So you can't just combine
15 two references when one explicitly says don't do that.

16 JUDGE WALSH: Why not?

17 MS. LYNCH: Because the Federal Circuit has found that if -- you
18 have to consider the references as a whole and any portion that teaches away
19 has to be considered. So by teaching something that has to be a minimum of
20 3, it teaches away from something that's less than 3.

21 JUDGE WALSH: But Federal Circuit also says, though, that the
22 teachings of the various references have to be weighed against each other.
23 Even when one seems to be in contradiction with another, one can fairly
24 weigh the disclosures, so why isn't the Examiner right to listen to *McEwen*?

25 MS. LYNCH: Because in that effect he's using *McEwen* just for
26 arginine, which Appellants argue teaches away. And in fact, *McEwen*

1 doesn't even reference proline. So to arrive at the present invention, now
2 we're using *Gray*, which teaches away from *McEwen*, which doesn't even
3 mention proline. And in fact, *McEwen* doesn't give a reason why they use 1
4 percent arginine. It seems to be entirely random, and for that reason, in
5 addition to teaching away, we would submit that it's not a proper
6 combination of the two references.

7 JUDGE PRATS: Why isn't *McEwen*'s teaching, that you can use 1
8 percent arginine, why isn't that at least an obvious to try situation in the KSR
9 sense?

10 MS. LYNCH: I would say clearly because *Gray* says you can't. So
11 maybe if you had combined *McEwen* with something else, maybe that would
12 make sense. But when *Gray* specifically says don't do this, that to me is a
13 very clear -- you know, if the skilled artisan is reading *Gray*, he's not going
14 to say oh, well, it tells me don't do this because it could -- you know,
15 because you need more than that but, what the heck, I'm going to try
16 something that's significantly less than that.

17 JUDGE WALSH: Could you point again to the passage where *Gray*
18 says don't use less than --

19 MS. LYNCH: I'm sorry, perhaps I'm being a little too informal. I
20 didn't mean to say that they say expressly don't do this, but I could point you
21 to a few places in *Gray*. If you look at *Gray*, column 4, lines 54 through 56,
22 they talk about providing a high arginine content. They list a few other
23 amino acids there, but they talk about a high arginine content. And if you go
24 on to column 5, the very top of column 5, it says that the present invention
25 "maximizes the natural available levels or amino acids such as arginine."
26 And then if you look at column 6, lines 60 through 62, it says "Enhanced

1 wound healing with arginine is believed to be provided at quantities greater
2 than 3 percent of the total calories." So there are several places in *Gray*
3 where they're saying at least 3 percent, preferably greater than that, we're
4 going to maximize that.

5 So those are the various places in *Gray* where the skilled artisan
6 would say okay, minimum 3.0, but I probably don't want to go anywhere
7 below that. So for that reason, Appellants would say that combining with
8 something that uses 1 percent just doesn't make sense unless you've got the
9 claimed invention in front of you, using a hindsight reconstruction to say
10 well, let's try it anyway, even though *Gray* teaches me not to.

11 JUDGE LEBOVITZ: So looking at *Gray* alone, because it says at
12 least 3 percent, the obvious to try rationale, at least by *Gray* alone, doesn't
13 work because why would it be obvious to use less when he's pointing you to
14 a upper -- a lower limit that exceeds the limit in the Claim. That would be
15 your position?

16 MS. LYNCH: Yes, that's exactly right. So maybe, you know, the
17 Examiner could've used a different reference. Like you were saying, why
18 isn't it obvious to try with *McEwen* at 1 percent? Maybe *McEwen* was
19 something else, but the combination of these two specific references just
20 doesn't seem to, you know, combine well, improper.

21 Those are the main points that I really wanted to hit, so are there any
22 other questions that I could answer for you guys?

23 JUDGE LEBOVITZ: Any questions?

24 JUDGE PRATS: No.

25 JUDGE WALSH: No. Thank you.

26 MS. LYNCH: Thanks.

1 JUDGE LEBOVITZ: The hearing is adjourned and we're off the
2 record.

3 (Whereupon, the proceedings, at 1:29 p.m., were concluded.)
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